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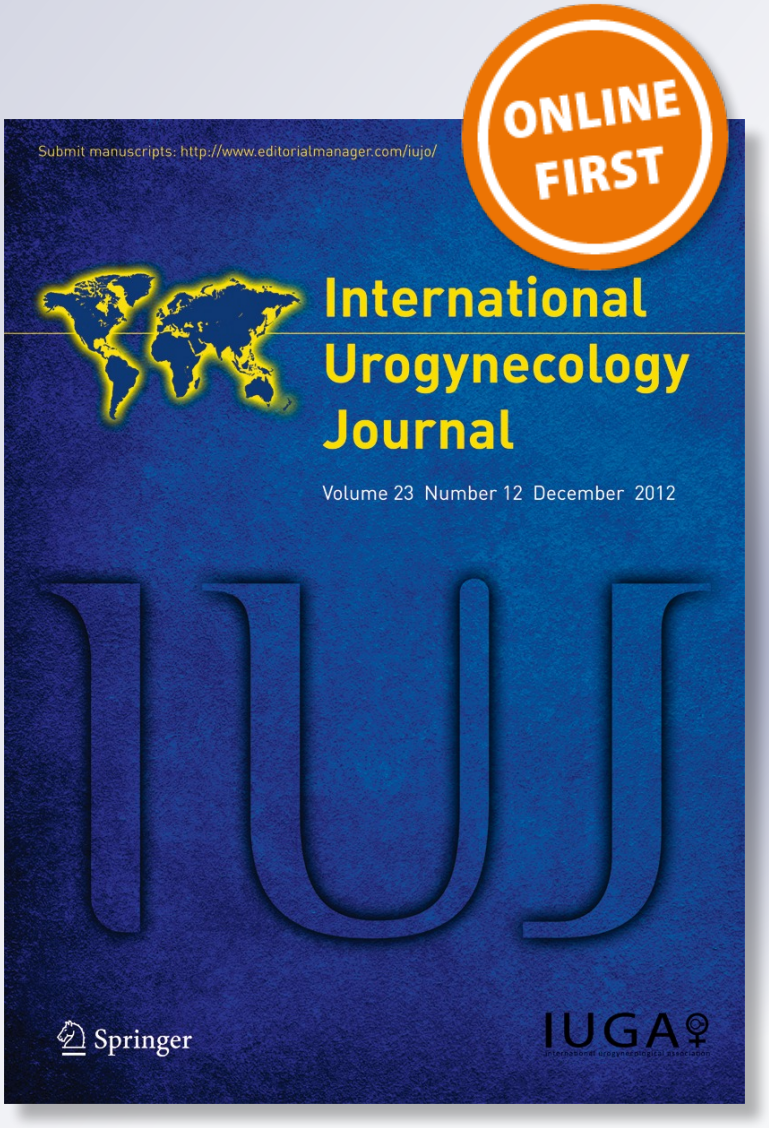
International Urogynecology Journal
Including Pelvic Floor Dysfunction

ISSN 0937-3462

Int Urogynecol J
DOI 10.1007/s00192-012-2007-5



Springer

Int Urogynecol J
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ORIGINAL ARTICLE

An inelastic retropubic suburethral sling in women with intrinsic sphincter deficiency

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Received: 19 July 2012 / Accepted: 12 November 2012

Abstract
Introduction and hypothesis We evaluated outcomes of an inelastic retropubic sling in patients with intrinsic sphincteric deficiency (ISD).
Methods This is a retrospective review of women diagnosed with ISD according to urodynamic parameters who underwent a retropubic suburethral sling surgery using a tape with minimal elasticity. All patients in the study where followed up at 2, 6, and 24 weeks and yearly. Outcome measures included self-assessed satisfaction, daily incontinence episodes and pad usage, standardized stress test, postvoid residual volume, and surgical complications.
Results Two hundred and forty-seven patients were involved in this study, with a median follow-up of 43 [interquartile range (IQR) 22–77] weeks and a minimum of 12 weeks. Two patients (0.008 %) had a positive stress test postoperatively. There was a decrease in daily incontinence events (median 1.5–0) ($p<0.001$) and pad usage per day (median 1.5–0) ($p<0.001$). Two hundred and sixteen (87.4 %) patients reported subjective improvement in symptoms. Urinary retention was found in 18 (7.2 %) patients, and 19 (7.7 %) patients required reintervention, mostly with bulking agent injections for persistent incontinence. No tape-related mesh exposures were reported.
Conclusion Retropubic suburethral inelastic slings represent a good option for treating patients with ISD, with satisfactory continent rates and low postoperative complications.

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Published online: 11 December 2012

Keywords Intrinsic sphincteric deficiency · Stress urinary incontinence · I-STOP sling

Introduction

Although intrinsic sphincter deficiency (ISD) is a commonly used phrase, it is not consistently defined in the urodynamic literature [1]. What is clear, however, is that as the name states, the urethral sphincter fails to hold urine, producing involuntary leakage [2]. Approximately 30 years ago, McGuire defined ISD as the worst form of stress urinary incontinence (SUI) (type III), in which sphincter impairment was so significant that a minimal increase in abdominal pressure could lead to urine leakage [3]. Maximal urethral closure pressure (MUCP) of ≤20 cm H_2O and/or Valsalva leak-point pressure (VLPP) of ≤60 cm H_2O, a urodynamic measure described by McGuire, remain the accepted diagnostic criteria despite the controversy that exists about the definition of this condition [4].

Urodynamic parameters are the most objective means of assessing urethral function, although data available on the value of these parameters in predicting sling success, short- or long-term, is limited. However, women with a VLPP or MUCP in the lowest quartile are nearly twofold more likely to experience SUI 1 year after transobturator or retropubic midurethral sling placement [5].

There have been substantial improvements in the treatment of female SUI (SUI). However, ISD is still associated with a high incidence of surgical failure [2]. Success rates with transvaginal tape (TVT) or transobturator sling (TOT), the most commonly used slings in ISD patients, range between 50 % and 86 % in long-term follow-up studies [6–9]. In an attempt to improve outcomes, several

novel slings have become available with different tape characteristics (elasticity, flexibility, variation in material), as well as different implantation techniques (adjustable, helical, etc.), each one with its touted benefits and risks. Reduction in elasticity may be beneficial because unlike high elasticity slings that deform under strain, an inelastic sling allows individualized tensioning in patients in whom some tension may be beneficial due to poor urethral function.

We performed a retrospective study to evaluate outcomes of patients diagnosed with ISD who underwent suburethral sling procedures with an inelastic [10] type I polypropylene sling [11] placed at the proximal urethra via a retropubic approach.

Materials and methods

Patients with urodynamically proven SUI with ISD who underwent a suburethral sling procedure with an inelastic monofilament, macroporous sling with looped edges (Fig. 1) (I-STOP, CL Medical, Lyon, France) between February 2007 and November 2011 at the Cleveland Clinic, Florida, USA, with a minimal follow-up of 12 weeks, were reviewed. The institution's comprehensive urogynecological database was queried for patient data after obtaining Institutional Review Board approval.

Inclusion criteria for sling placement were based on urodynamic parameters with a MUCP of ≤40 cm H_2O and/or a VLPP at ≤60 cm H_2O capacity and urethral hypermobility [4]. These urodynamic parameters were chosen because MUCP and VLPP are commonly used tests to assess urethral function. MUCP of 40 cm H_2O was chosen based on our center's data on a higher failure rate of transobturator slings with MUCP ≤40 cm H_2O and/or VLPP at capacity ≤60 cm H_2O [4]. Self-reported pad usage per day was not used as a study inclusion criterion, as it is an unreliable measure of incontinence severity with a significant age bias [12]. Older patients have been previously reported to have a higher gram per pad urinary loss into fewer total pads [12].

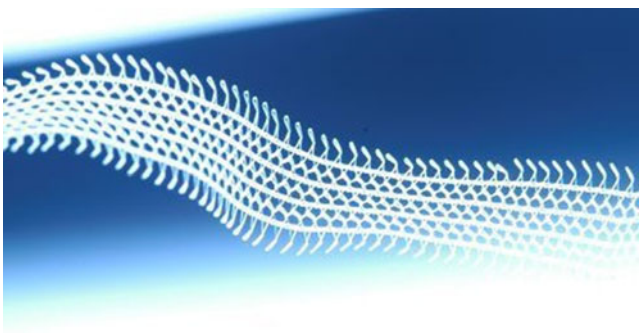

Fig. 1 Mesh used for the I-STOP sling

All patients were examined by the primary surgeon prior to surgery and evaluated at the postoperative follow-up visits by one of five clinicians, including postgraduate fellows. Patient data consisted of demographic variables such as age, body mass index (BMI), gravidity, parity, menopausal status, and tobacco use. Urogynecologic symptomatology, including incontinent events and pad usage per day and past urogynecologic procedures was recorded. Preoperative evaluation included physical examination to determine vaginal support anatomy and degree of urethral mobility via a Q-tip test, urinalysis and culture, and empty supine stress test (ESST). Multichannel urodynamic testing was performed using air-charged catheters and routine technique in all patients [13]. All surgical procedures were performed by two experienced urogynecologic surgeons. Perioperative factors considered were type of anesthesia, blood loss, concomitant procedures, and complications.

Follow-up visits where scheduled at the 2, 6, and 24 weeks postoperatively and then yearly. At each visit, data collected included reporting of subjective satisfaction, incontinent events and pad usage per day, standardized stress test, pelvic examination, postvoid urine residual measured by ultrasound (US), urinalysis, and sexual activity symptoms. The standardized stress test was performed with 250 cc of urine in the bladder in supine and standing (if no leakage when supine) positions. Incontinence events and pad usage were reported. Bladder diaries were not routinely completed, and quality of life questionnaires were not used routinely. However, patients completed a 5-point standardized global improvement scale comprising cured, greatly improved, improved, not improved, worsened, which was administered on intake by a clinic nurse. Subjective success was defined as cured or greatly improved. Outcome measures analyzed were daily incontinence episodes and pad use, stress test results, the 5-point standardized global improvement scale, postvoid residual urine volume, and perioperative and postoperative complications.

Statistical analysis was performed using PASW STATISTICS 18 (SPSS, Chicago, IL, USA). Continuous variables were tested for normality using Shapiro–normality test. Normal continuous data was described as mean and standard deviation (SD), with 95 % confidence interval (CI), and abnormal continuous data was described as median and interquartile range (IQR). Normal continuous variables were analyzed with paired *t* test, and abnormal data was analyzed with Wilcoxon signed rank test. Categorical data was analyzed using the chi-square test. Fisher's exact test was used if the value of any cell in the 2 × 2 contingency table was <5. A p value<0.05 was considered significant.

Operative technique

Proximal urethral placement of the sling was based on previously reported pubovaginal sling techniques, which have been described as indicated for severe SUI or ISD. This technique is designed to mimic the mechanism of such traditional pubourethral slings [14]. The surgical approach for I-STOP sling is similar to other retropubic slings. Two small (1-cm) incisions were made 2 cm above and lateral to the pubic symphysis for later passage of the sling needles. The anterior vaginal wall was infiltrated with 1 % lidocaine with epinephrine and incised vertically suburethrally for a length of 3 cm. The endopelvic fascia was dissected off the vaginal mucosa bilaterally to the vaginal sulcus and urogenital diaphragm. This allowed sufficient bladder-neck mobility such that the desired sling tension could be achieved by the surgeon. The sling needles were guided ipsilaterally through the urogenital diaphragm and space of Retzius and through the suprapubic incisions. Cystoscopy was performed to rule out injury to either urethra or bladder. A suprapubic catheter was placed under cystoscopic visualization, if required. The ends of the sling tape were then connected to the needles, and both needles were pulled upward through the suprapubic incisions. The sling was secured by a suture to the proximal urethra. Sling tensioning was performed using a 21-F cystoscope held in a 45° angle to the horizontal plane [15]. The excess tape was cut just below the skin line. Closure of the suprapubic and vaginal incisions was accomplished with surgical glue and 2-0 Vicryl suture, respectively.

Results

Our query yielded 247 patients who had undergone I-STOP sling surgery for ISD during the study period. Table 1 displays patient demographic data. The vast majority were menopausal, with 75 % being older than 60.5 years and 25 % older than 78.0 years; 68.4 % were overweight (BMI >24.9), with 27.9 % categorized as obese (BMI >29.9). Thirty-three patients had undergone previous anti-incontinence surgery, with three having undergone more than one.

Preoperative urodynamic parameters were as follows: median (IQR) MUCP was 28 (20.5), VLPP at capacity 42 (27.5) cm H_2O, peak flow 14.6 (7.05) ml/min, mean flow 6 (4.45) ml/min, and detrusor pressure at maximal flow 10.2 (4.6) cm H_2O. Median blood loss was 100 ml (IQR 50), with no events of postoperative hemorrhage or blood transfusion. One hundred twenty-eight patients (51.8 %) underwent spinal anesthesia, 118 (47.8 %) general anesthesia, and one (0.004 %) both. One hundred ninety-seven (79.8 %) patients had concomitant procedures; specific surgeries are listed in Table 2. There were few complications associated with surgical procedures or during the immediate recovery period. One patient developed a vaginal hematoma, which required drainage 6 weeks after the procedure, and one developed a rectovaginal fistula unrelated to the sling, which required reintervention. One bladder laceration with a sling needle was recognized during cystoscopy and required suturing during surgery without having any later consequences or affecting the patient's continence. There were no vaginal or bladder tape exposures reported during the follow-up period.

Median follow-up was 43 (IQR 22–77) weeks. Median number of postoperative visits was four (IQR 3–6). Table 3 shows subjective and objective outcomes after surgery; 87.4 % of patients reported being cured or improved; >71 % reported being cured at the last follow-up recorded; 12.4 % stated they did not improve or got worse.

Median number of incontinence events per day and pad usage revealed a significant decrease from preoperative to the postoperative values. Occult incontinence was reported in 85 (34.4 %) patients who had concomitant prolapse. The

Table 1 Demographic data (N=247 patients)

Variable	Value
Age[a]	69.4 (17.5)
Weight (kg)[a]	68.2 (15.3)
Height (m)[a]	1.60 (0.1)
BMI[a]	27.01 (6.0)
Parity[a]	2.00 (1.00)
Menopausal status	
Postmenopausal	221 (89.5 %)
Premenopausal	26 (10.5 %)
Smoker	
Never	187 (59.5 %)
Past + current	135 (40.5 %)
Previous surgeries	
TAH	76 (30.76)
TVH	31 (12.55)
Anti-incontinence surgery	33 (13.4)
Pelvic repair surgery	27 (10.9)

[a] Median (Interquartile range)

Table 2 Concomitant procedures

	Number	Percent
Hysterectomy	39	15.79
Anterior repair	108	43.72
Posterior repair	150	60.73
Abdominal apical suspension	8	3.24
Vaginal apical suspension	109	44.13

Table 3 Outcomes

Objective	Preop	Postop	*P* value
Incontinent events per day[ab]	3.5 (1.5–5.5)	0 (0–1.5)	<0.001
Pads per day[ab]	1.5 (1.5–3.5)	0 (0–1.5)	<0.001
Stress test positive	162 (65.5 %)	2 (0.008 %)	
Subjective			
Postoperative self-assessment satisfaction			
Cured/improved		216 (87.4 %)	
Not improved		17 (6.8 %)	
Worsened		14 (5.6 %)	

[a]Median (interquartile range)

[b]85 patients were excluded because of occult stress incontinence

remaining 162 (65.5 %) patients had a positive stress test during pelvic examination. All had urodynamically documented ISD. One hundred and twenty-five patients had mixed urinary incontinence (MUI) prior to surgery, of whom 40 had significant bother at 6 weeks following surgery and were given anticholinergic medication. Four patients developed de novo urge following surgery, of whom two reported symptoms 12 weeks following surgery but did not require medication; two developed urge 2 years after surgery and were given anticholinergic medication. Eighteen (7.2 %) patients had postvoid residual urine volume >100 ml at the last follow-up visit; 12 (66.7 %) of them were asymptomatic, and six (33.33 %) reported having voiding abnormalities (slow, interrupted, dribbling). The number of sexually active patients decreased from 100 (40.5 %) before to 80 (32.4 %) after the surgery. The proportion reporting dyspareunia among sexually active women remained similar, with 35 (35 %) prior to surgery and 30 (33.8 %) after surgery. Nineteen (7.7 %) patients required reintervention: 11 underwent bulking agent injection for persistent incontinence; five underwent sling takedown or transection for urinary retention. Sling transection was performed at least 3 months postoperatively to allow full integration of the sling arms and reduce the likelihood of recurrent SUI.

Discussion

The principal focus of our study was to evaluate the use of an inelastic suburethral sling in patients with ISD, a challenging, severe form of SUI. The I-STOP sling is a type I polypropylene, monofilament, macroporous, mesh tape [16] similar to the traditionally used synthetic slings except that it is woven to be much less elastic. It is now well known that monofilament tapes decrease the risk of infection compared with multifilament meshes [17]. Multifilament slings do not allow white blood cells to enter interstices between filaments <10 um, making infection more likely [18]. Monofilament slings have less risk of producing healing abnormalities (i.e., mucosal exposures) compared with multifilament slings (1.3 % vs. 6 %, respectively) [19]. I-STOP tapes are macroporous, which means that the pore size is >75 μm [17]. This allows fibroblasts, mononuclear phagocytes, and polymorphonuclear neutrophils to infiltrate through pores and create a better environment to permit tissue incorporation into the tape material [18].

As the I-STOP sling has lower elasticity [16], the surgeon may be able to apply tension more precisely. Its construct minimizes tape deformability, which may provide a more predictable postimplantation behavior [20]. It was initially thought that in order to prevent urinary retention, sling tapes had to have high elasticity, but new studies have proven otherwise [10]. Being inelastic, there may be less likelihood of tape shrinkage, which can lead to progressive retention and irritative bladder symptoms, possibly requiring sling revision. Another important characteristic of this tape is its high flexibility compared with other type I tapes, which have medium flexibility. This means it may have the capacity to bend, making it more malleable during surgery [20]. As a result, it may be more accurately tensioned and may lay flat without deformation suburethrally. Another unique characteristic of this tape is the presence of looped tape edges [20]. This may help decrease mucosal exposure into adjacent tissue and may improve tissue fixation. There were no vaginal exposures in our study, whereas in other studies in which TVT or TOT tapes were used, exposure rates were reported between 1.4 % and 3.8 % [6, 7, 21]. However, our median follow-up of 43 weeks was too short to make any definite conclusions regarding mesh exposure following I-STOP sling surgery. Also, the potential benefits of low elasticity and high flexibility need to be assessed in comparative studies.

Results of our study are encouraging when compared with other published articles on the use of suburethral slings for ISD treatment. Gungorduk et al. reported an overall cure rate of 52.5 % with TOT and 78.3 % when using TVT [7]. Similarly, Choo et al. reported a success rate of 76.6 % after

a minimum follow-up of 3 years in ISD patients using TVT [6]. In both those studies, however, the mean age was 50.6 and 58.7 years, respectively. Doo et al. found an overall cure rate of 50 % after 5 years of follow-up in a retrospective study of 134 patients with VLPP of ≤60 cm H_2O treated with TVT [8]. A retrospective study by Jeon et al. found that cure rates following TVT in ISD patients decreased from 86.94 % to 55.09 % between the 2- and 7-year follow-up [22]. On the other hand, Rezapeur et al. reported an overall improvement of 86 % using TVT in a prospective study [9]. However, the majority of patients in whom TVT failed were >70 years of age. It must be noted that almost 50 % of patients in our study were >70. This supports the fact that the incidence of ISD increases as women age, as does SUI severity.

In a randomized controlled trial of 164 patients, Schierltz et al. compared the efficacy of TVT and TOT in patients with ISD. They reported a 45 % and 21 % failure rate 6 months after surgery in TOT and TVT, respectively. Similarly, when an intention-to-treat analysis was undertaken, they found that one of every six patients with TOT and one of every 16 patients with TVT would have required surgical reintervention for further correction [23]. Sling tensioning with a cystoscope at a 45 ° angle was based on a study by Ostermann et al., in which the MUCP was measured intraoperatively while performing the sling tensioning procedure. The authors reported that using this technique for tensioning, there was a normalization of MUCP when the scope was held at a 45° angle without excessive tensioning, which could lead to urinary retention [15].

There were 19 (7.7 %) patients who required reintervention in our study. In contrast, Araco et al. reported a 17 % reoperation rate: 12 for bladder obstruction and 17 for failure to cure incontinence [24]. Intervention was uncommon in our patients. We were very careful during tensioning to avoid overcorrection. That may explain the need to perform bulking agent injections in patients with persistent SUI.

Urinary retention is the most frequent complication in sling surgery for SUI [25]. In our study, 18 (7.2 %) patients had urinary retention at the last recorded visit, with five (1.6 %) patients requiring sling takedown with simple transection. Studies involving TVT slings have reported a similar or higher retention rate and sling removal. Wang et al. reported a 26 % rate of voiding dysfunction after undergoing a TVT procedure for SUI or MUI [26]. Similarly, Abouassaly et al., in a retrospective study using TVT sling, reported a 32 % rate of retention longer than 48 h, 20 % requiring intermittent catheterization and 4.5 % required sling takedown or transection for urinary retention [27]. Guezzi et al. reported voiding difficulties in 25.7 % of patients, with 5.7 % of the patients requiring sling takedown [28].

Our study is not exempt from weaknesses. It was a retrospective study without comparison to a control group or the use of validated questionnaires. Inclusion criteria were based on urodynamic parameters, and hence, a proportion of our study patients had occult incontinence. However, a previous study that established that poor urethral function, as determined by urodynamic parameters, is associated with sling failure also included 20 % with occult incontinence. Thus, the presence of occult incontinence in our study population may not be a confounding factor for assessing the efficacy of the I-STOP sling. Median follow-up was 43 weeks. This could be considered a short-term follow-up, and there should be a delayed analysis performed of the same group of patients to determine long-term outcomes of this sling.

Conclusion

From the results of this investigation, we can conclude that an inelastic retropubic suburethral sling is effective for patients with ISD. Further research is necessary using this type of sling in a randomized, prospective, comparative trial to corroborate these findings.

Conflicts of interest GW Davila: honoraria, American Medical Systems, CL Medical, Astellas, Warner-Chilcott; consultant, American Medical Systems, Coloplast, CL Medical, Astellas; research funding, CL Medical. Other authors: No conflict of interest

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